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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,717	10/06/2003	Ira Mark Smith	SMITH-LUTL	2891

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HINKLE & O'BRADOVICH, LLC
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EXAMINER

DOSTER GREENE, DINNATIA JO

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/679,717	Applicant(s) SMITH ET AL.	
	Examiner Dinnatia Doster-Greene	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2003 and 15 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 15-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Detailed Action</u> . |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 21 is drawn to the combination of a brace comprising a temperature pad.

II. Claims 1-20 and 22-25 are drawn to the subcombination of a brace comprising a thermally conductive sheet, a temperature controller or a temperature control circuit.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions of Group I and Group II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the claims of the subcombination require either a thermally conductive sheet, a temperature controller or a temperature control circuit. The subcombination has separate utility such as temperature regulating devices.

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3. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

4. In the event that applicant chooses Group II, he/she is required to further elect between the subcombinations as defined below.

Group III. Claims 1-14, drawn to an orthopaedic brace comprising a thermally conductive sheet, classified in class 219, subclass 529.

Group IV. Claims 15-20, drawn to a back brace comprising a temperature pad and a temperature controller, classified in class 2, subclass 92.

Group V. Claim 22, drawn a self-contained heating and cooling kit, classified in class 62, subclass 3.5.

Group VI. Claims 23-25, drawn to a temperature control circuit, classified in class 607, subclass 98.

Inventions of Group III, Group IV, Group V and Group VI are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention of the subcombination has separate utility such as follows. Group III can be used as an electric blanket or a warming pad. Group IV can be used as body comforter or a back protector. Group V can be used as a device which uses an electrical effect to product both a heating and cooling treatment such as a flexible heat exchanger material. Group VI can be

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used as a device which supplies an electrical current in a localized manner such as a temperature control circuit in a circulation warmer. See MPEP § 806.05(d).

5. Through telephonic communications with Greg O'Bradovich on November 9, 2004 a provisional election was made with traverse to prosecute the invention of the **Subcombination of Group III, claims 1-14**. Affirmation of this election must be made by applicant in replying to this Office Action. **Claims 15-25** are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Information Disclosure Statement

6. Contradictory statements were made in the Information Disclosure Statement filed on October 6, 2003. Page 2 of the information disclosure statement filed states that "3. Copies of Listed Information Items Accompanying This Statement" were submitted. However, in the Preliminary Statements of Section 1, the Applicant stated that "Applicant know[s] of no prior art at this time." Since no prior art references were listed or filed with the information disclosure statement, Applicant's intent is unclear as to why this paper was submitted in the application.

Claim Objections

7. Claims 1, 2, 7 and 13 are objected to because of the following informalities:

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In order to improve the clarity of claim 1 and to make it more consistent with claims 3 and 4, the Examiner suggests that the phrase "a thermally conductive sheet connected to each of the first and second surfaces" be changed to "a thermally conductive sheet connected to the first surface and a thermally connected sheet connected to the second surface."

Claim 1 should end with a period instead of a semi-colon.

Claims 2 and 13 recite the limitation "the sheet" in claim 2, line 2 and claim 13, line 5. There is insufficient antecedent basis for this limitation in the claim.

Claim 7 should end with a period.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 4, 5 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Taylor et al. (U.S. Patent No. 6,125,636).

As to claim 1, Taylor discloses in Fig. 3 a temperature element (80) and a thermally conductive sheet (90, 110) connected to a first and second surface of the temperature element.

As to claim 4, Taylor discloses in column 5, lines 11 – 26 the use of a thermal grease located between the first surface of the temperature element (80)

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and the thermally conductive sheet (90) and the thermal grease located between the second surface of the temperature element and the thermally conductive sheet (110).

As to claim 5, Figs. 4a-5a illustrate the operation of the temperature controller connected to the temperature element.

As to claim 6, the temperature element (80) in Taylor is a Peltier thermovoltaic module.

10. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being unpatentable over Klein (U.S. Patent No. 4,930,317).

Klein discloses in Fig. 5a and column 7 a temperature element 132, 134 or 136, a thermally conductive sheet 130 attached to the first and second side of the temperature elements and a thermally insulating sheet 38 (the pad cover,, Klein column 7, lines 37 – 48). When the device of Klein is fully assembled, the aperture of the pad cover 38 surrounds the temperature element 132, 134 or 136 while the pad cover 38 is positioned between the thermally conductive sheet 130 (Klein, column 3, lines 53-64). The recitation of an “orthopaedic brace” in the preamble has not been given any patentable weight since the body of the claim does not amplify the “orthopaedic brace.”

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to

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be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brunswick (U.S. Patent No. 4,716,892).

As to claims 7-8, Brunswick discloses an orthopaedic brace having a main body with a outer and inner surface and an opening. The brace also comprises a plurality of straps, fasteners and buckles. Although the brace of Brunswick does

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not discloses the exact configuration as recited in the claims, the Office takes Official Notice that the number of primary and secondary straps that may be employed in an orthopaedic brace is a matter of design choice which can depend entirely upon the body part which is being wrapped. Furthermore, a review of the specification did not reveal any criticality to the configuration of the straps and buckles. Thus, the design configuration of the brace recited in the claims would have been obvious to one skilled in the art in view of the brace disclosed in Brunswick.

As to claims 9-10, Brunswick further discloses an pocket connected to the inner surface of the main body and including a front and rear panel. The rear panel is connected to the inner surface of the main body.

13. Claims 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brunswick (U.S. Patent No. 4,716,892) in view of Brink (U.S. Patent No. 5,741,220). Brunswick discloses the claimed invention as discussed above, with the exception of the front panel of the pocket being mesh. Brink, which also discloses a orthopaedic brace including a pouch or pocket 34, discloses that the pocket contains a mesh front panel 36. Thus, it would have been obvious to one skilled in the art at the time of the invention to modify the pocket of Brunswick with the mesh panel disclosed in Brink for the purpose of providing a temperature barrier which is porous enough to allow the temperature flow that is needed while providing the desired temperature as taught by Brink.

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14. Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brunswick (U.S. Patent No. 4,716,892) in view of Goldsmith (U.S. Patent No. 5,407,421) in view of Klein (U.S. Patent No. 4,930,317).

As to claims 12-14, Brunswick discloses the claimed invention with the exception a thermally conductive sheet connected to a first and second side of a temperature element, a thermally insulating sheet located between the thermally conductive sheets, the temperature element being located within the sheet and thermal adhesive located between the first surface and the thermally conductive sheet and the second surface and the thermally conductive sheet. Brunswick also fails to disclose a temperature controller connected to the temperature element. Goldsmith, like Brunswick, relates to a brace comprising an inner pocket (24, 25) containing a removable thermally responsive material 72 (Fig. 5) for applying hot and cold therapy (Goldsmith, Abstract). Klein, similar to Goldsmith, discloses a thermally conductive apparatus for applying localized heat and cold therapy. Since the pockets in Brunswick contains a metal plate 16 (a thermo-formable bracing element 16) which is inherently a thermally conductive sheet, based upon the teaching of Goldsmith, it would have been obvious to one skilled in the art at the time of the invention to substitute the metal plate 16 in Brunswick with the hot/cold pad assembly of Klein for the purpose of providing localized heat and cold therapy.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Peters (U.S. Patent No. 5,836,903); Williams

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(U.S. Patent No. 5,415,624); Haas et al. (U.S. Patent No. 6,074,414); Altura (U.S. Patent No. 6,613,953); Grim et al. (U.S. Patent No. 4,964,402), Carson (U.S. Patent No. 6,375,674); Courtnage et al. 2002/0143373A1 and Pira (U.S. Patent No. 6,017,337).

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dinnatia Doster-Greene whose telephone number is 703-308-1041. The examiner can normally be reached on 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*ddg**

Henry Bennett
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Group 3700